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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,307

07/30/2003

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EXAMINER

BUI, VY Q

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PAPER NUMBER

3773

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,307	Applicant(s) WASDYKE, JOEL M.	
	Examiner Vy Q. Bui	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-22, 24, 31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-22, 24, 31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

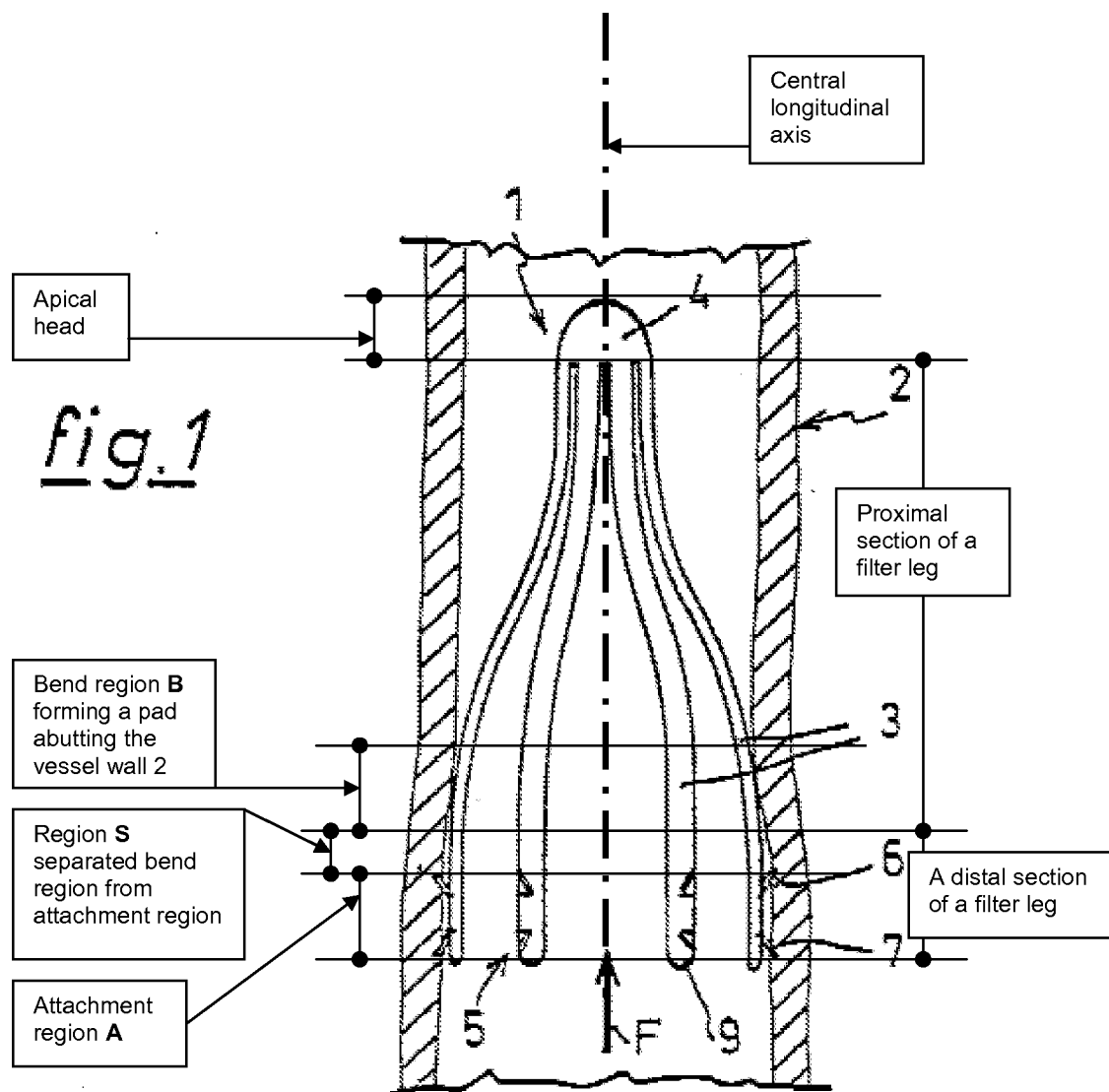
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, 24 and 31, 33-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lefebvre-5,108,418.

As to claims 13-15, 24 and 31, 33-34, Lefebvre-‘418 (Fig. 1-3; abstract; line 52, col. 2 to line 4, col. 4) discloses filter device made of a shape memory/elastic material having six legs 3 joined together to form head 4, means for attachment/hooks 6, 7 (Fig. 2-3) and a bend region in the proximal section forming a pad to abut the vessel wall (Fig. 1). Legs 3 of the device may be brought substantially against one another in a sheath for introduction, and they expand out inside the vein 2 when the filter is pushed out of the sheath. The elastic deformation of the legs 3 with respect to the head 4 is such that, when the filter 1 is implanted, each legs 3 abuts on the inner wall 8 of the vein 2 at region B (reproduced Fig. 1, below). Notice that from Fig. 1 below, the bend region of legs 3 are longitudinally apart from the attachment region (region having attachment means/hooks 6, 7) by region S. Inherently, six legs 3 are symmetrically or substantially 60-degree apart from one another in a lumen of a blood vessel to conform to the lumen of the blood vessel and distribute the applied forces on the vessel wall evenly.

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Alternatively, it would have been obvious to one of ordinary skill in the art to arrange six legs 3 60-degree equidistance apart in a symmetrical configuration to substantially evenly conform to a lumen of a blood vessel and evenly distribute the applied force of legs 3 on the vessel wall.



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As to claims 35-35, one can selectively choose a proximal section having no contact to the vessel wall when the filter is expanded in a filter configuration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 16-17, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefebvre-5,108,418 in view of Simon-4,425,908.

Lefebvre-'908 discloses substantially the claimed invention, except for the shape memory material of the device is a nickel-titanium-cobalt alloy. However, Simon-4,425,908 (Fig. 1-13; abstract; line 25, col. 5 to line 9, col. 6) discloses a filter device includes filter legs 22, hooks 26, bend regions/pad 20 of an alloy of Ni-Ti (nitinol) having a pliable (martensite) condition at a temperature below 70 degrees F and expand to a rigid (austenite) condition at above 90 degrees F. It would have been obvious to one of ordinary skill in the art at the time of the invention to make Lefebvre-5,108,418 blood filter of a Ni-Ti-Cobalt alloy as taught by Simon-'908 as this material is well known and proper for making a blood filter device.

2. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lefebvre-5,108,418 in view of Simon-4,425,908 and further in view of Boylan et al-6,602,272.

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Lefebvre-5,108,418 in view of Simon-'908 discloses substantially the claimed invention, except for the shape memory material of the device is a nickel-titanium-cobalt alloy. However, Boylan-272 (claims 8 and 21) discloses a blood filter device comprising a Ni-Ti-Cobalt alloy. It would have been obvious to one of ordinary skill in the art at the time of the invention to make a filter as taught by Lefebvre-5,108,418 in view of Simon-4,425,908 of a Ni-Ti-Cobalt alloy as this material is well known and proper for making a blood filter device as taught by Boylan et al-6,602,272.

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lefebvre-5,108,418 as applied to claim 13 above in view of Mazzocchi et al.-6,949,103.

Lefebvre-5,108,418 discloses substantially the claimed invention, except for the lubricious coating of the device. However, Mazzocchi-'103 (col. 12, lines 7-22) discloses that it is well known to have a lubricious coating to control thrombogenicity of a blood filter. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a lubricious coating for the Simon-'908 blood filter device as recited in the claims for this configuration is well known in the art for controlling the thrombogenicity of the blood filter device.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 35-36 dependent to claims 13 and 24 respectively each recites

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“wherein each filter leg **does not contact** the wall of the blood vessel in **the proximal section** of the filter leg in the filtering configuration.”. This limitation contradicts to independent claims 35-36, which each recites “a bend region **in the proximal section** forming a pad configured **to abut the vessel wall**”. Correction is required.

Response to Arguments

Applicant's amendment and arguments with respect to the claims of present invention have been carefully considered but are not convincing.

A. 102/103 Rejection:

1. The Applicant argued that “Clearly, the bend region indicated by the Examiner in Fig. 1 is not in the proximal section of the elongated filter legs” (last paragraph, page 5 of 8, Remarks/Arguments; paper 12/31/2008).

However, the language of the independent claims 13 and 24 do not exclude the case when the proximal section is longer than the distal section as shown in reproduced Fig. 1 above.

2. The Applicant argued that: “the bend regions asserted by the Examiner are not spaced longitudinally apart from the attachment regions as claimed in independent claim 24. The bend region asserted by the Examiner appears to be adjacent the attachment region. Therefore, Applicant believes that claim 24 is novel and non-obvious over Lefebvre” (2nd paragraph, page 6 of 8, Remarks/Arguments; paper 12/31/2008).

However, as shown in reproduced Fig. 1 above, there exists region S separating bend region B and attachment region A.

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B. 103 Rejection:

Applicant argued that 102/103 rejections of claims 13-15, 24 and 31, 33-34 over Lefebvre-'418 were improper. Therefore, the rejection 103 of claims 16-17 and 19-21, which are dependent to independent claims 13 and 24 are also improper.

However, as indicated above, the 102/103 rejections of claims 13-15, 24 and 31, 33-34 over Lefebvre-'418 were improper. Therefore, the 103 rejections of claims 13-15, 31, and 33-34 are also proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/

Primary Examiner, Art Unit 3773